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June 18, 2014

Via Federal Express
TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): Results of an acute eye irritation study in rabbits with an experimental pesticide

Dear Section 8(e) Coordinator:

[redacted] is submitting the results of an acute eye irritation study in rabbits with an experimental pesticide containing two active ingredients, conducted by [redacted].

Active Ingredients:
1. [redacted]
2. [redacted]

The potential of the test substance to cause damage to the conjunctiva, iris or cornea was assessed by a single ocular application of 0.1 mL of the test item to one eye of three White New Zealand rabbits (stepwise procedure starting with one animal and supplementing two additional animals). About 24 hours after application the eye was rinsed with tap water.

The ocular reactions were assessed approximately 1, 24, 48 and 72 hours after application and in weekly intervals until day 7 or 28, respectively.

The following test item-related clinical observations were recorded during the course of the study:

- Slight to moderate corneal opacity (grade 1-2)
- Moderate iritis (grade 1)
- Slight to obvious conjunctival redness (grade 1-2)
- Slight to marked conjunctival chemosis (grade 1-3)
- Slight to severe discharge (grade 1-3)
- Additional findings like contracted pupil, hair loss, swelling of the sclera, desquamation of corneal epithelium, rough cornea, corneal lesions after instillation of fluorescein (grade 1-4), marginal vascularization of the cornea in a circumscribed area as well as vascularization into the central part of the cornea in a circumscribed area and injected scleral vessels in a circumscribed or circular area were noted in the animals within 7 days (two animals) or 28 days (one animal), respectively.

In two animals the ocular reactions were reversible within 7days after application.
The ocular reactions were not reversible in one animal within 28 days after application. Moderate corneal opacity (area involved > ¼ < ½), slight redness of the conjunctiva, slight discharge and desquamation of corneal epithelium, rough cornea, corneal lesions after instillation of fluorescein (grade 2), injected scleral vessels in a circumscribed area and vascularization into the central part of the cornea in a circumscribed area were still observed in this animal at study termination on day 28.

Mean scores calculated for each animal over 24, 48 and 72 hours were 1.3, 2.0 and 2.0 for corneal opacity, 1.0, 1.0 and 1.0 for iris lesions, 2.0, 2.0 and 2.0 for redness of the conjunctiva and 1.0, 1.0 and 2.0 for chemosis.

Considering the described ocular reactions as well as the irreversibility observed in one animal, the test substance causes serious eye damage under the test conditions chosen.

[redacted] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,